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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,977	KIEL ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,31-48 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,31-48 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *23 May 2006*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21, 31-48 and 53 are presented for examination.

Applicant's Amendment filed August 14, 2006 has been received and entered into the present application.

Claims 1-21, 31-48 and 53 remain pending and are under examination. Claims 22-30 and 49-52 are cancelled and claims 1-3, 5-7, 9-20, 31-48 and 53 are amended.

Applicant's amendments to claims 32-48 changing the preamble of the claim from the "process of claim 31" to the "composition of claim 31" has been noted. Applicant submits that the recitation of "process" in these claims was in error and that said claims were intended to be composition claims. Applicant has requested examination of these claims as being directed to the elected subject matter.

Accordingly, Applicant's request for examination of claims 31-48 as being directed to composition claims has been considered and is granted. Prosecution of the present case will proceed insofar as the claims read upon composition(s) of matter, i.e., claims 1-21, 31-48 and 53.

Applicant's amendments and arguments, filed August 14, 2006, have been fully considered. In consideration of the amendments that have been made to the claims, the rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied as a result of Applicant's amendments to the claims. They constitute the complete set of rejections presently being applied to the instant application.

Applicant's Claim for Priority under 35 U.S.C. 120

Applicant's traverse the Examiner's determination to deny priority to U.S. Patent Application No. 10/047,578, stating that, "Applicants submit that claiming the benefit of a prior-filed application under 35 U.S.C. 120 is a legal matter that is ultimately determined by a comparison of the issued claims to the disclosure of the '578 application. Thus, Applicants submit that such a determination is not within the

purview of the Examiner, but rather, will be determined by a Court, should the issue arise. In any event, because there are no issued claims in the present application as of yet, Applicants submit that any discussion of a claim of priority is premature. Applicants therefore request that the denial of the claim for priority be withdrawn." (see pages 18-19 of Applicant's remarks)

Applicant's traversal has been considered, but does not change the determination of priority by the Examiner. Priority is an issue that must be determined by the Examiner in order to establish the effective filing date of the application and to apply the appropriate prior art that is material to patentability of the claimed invention(s) at the time the invention was made.

In the present case, the disclosure of the '578 application fails to disclose the incorporation of the dextromethorphan active pharmaceutical ingredient as a component of the claimed composition. In light of such, Applicant's request for priority under 35 U.S.C. 120 to the '578 application has been reconsidered, but is again denied. The effective filing date of the present application is maintained as August 22, 2003.

Claim Rejections - 35 USC § 112, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Present independent claims 1, 31 and 53 are each drawn to a composition comprising a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan, wherein the composition is produced by the process of forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients in a solvent, forming a dispersion by mixing a dispersing agent and tannic acid in a solvent and combining the solution and the dispersion to form tannate salts of the active pharmaceutical ingredients and then combining the tannate salts with at least one suspending agent without isolation or purification to produce a homogeneous suspension of the pharmaceutically active tannate salts.

Applicant has failed to direct the Examiner to a specific portion(s) of the specification that provides adequate written support for each of the newly added claim limitations. Accordingly, the Examiner has reviewed the present specification and claims as originally filed to determine whether Applicant was in possession of each and every newly added limitation at the time of the present invention.

In particular, Applicant has failed to provide adequate written support for the claimed limitations directed to (1) a plurality of active ingredients (claims 1, 31 and 53), (2) plurality of dosage units (claims 1, 31 and 53), (3) combinations thereof (claims 3, 5, 32, 34-37 and 39-43), (4) at least one tablet excipient (claim 31) and (5) homogeneous suspension, granulation or composition (claims 1, 31 and 53).

Regarding Applicant's newly added limitation to "a plurality" of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine and dextromethorphan (claims 1, 31 and 53), the specification and claims as originally filed fail to provide adequate written support to now broaden the claim to encompass a "plurality" of active pharmaceutical ingredients. The claims as amended now read upon a composition including the phenylephrine, pyrilamine and dextromethorphan components in addition to other unspecified active pharmaceutical ingredients that are not recited nor identified in the specification and claims such that one of ordinary skill in the art would have immediately envisaged what other active pharmaceutical ingredients were intended by the limitation of "a plurality".

Additionally, while the use of the transitional phrase "consisting essentially of" may be construed as limiting the claims only to the phenylephrine, pyrilamine and dextromethorphan components as recited in the claims, it is noted that Applicant has failed to clearly indicate what the novel and basic characteristics of the invention are such that the identity of those components that he intends to exclude from the claims would be readily identified. In the absence of such disclosure, the phrase "consisting essentially of" is properly interpreted, according to MPEP §2111.03, as open language and, therefore, allows for the inclusion of additional active pharmaceutical ingredients. Given that Applicant has limited his disclosure only to compositions comprising phenylephrine, pyrilamine and dextromethorphan, the newly added limitation to "a plurality" is a broadening of the claimed subject matter that does not have adequate written support in the original disclosure.

Regarding Applicant's newly added limitation directed to "a plurality of dosage units" (claims 1, 31 and 53), the specification fails to provide adequate written support for this limitation. The specification discloses that the pharmaceutical composition as presently claimed is prepared in a single dosage form, not as a plurality of dosage forms. In particular, the specification states, "In accordance with the present invention and the contemplated problems which have and continue to exist in this field, the present invention provides a manufacturing method for in-situ conversion and incorporation of tannate salts of pyrilamine, phenylephrine, and dextromethorphan in a single dosage form. The present invention also provides for pharmaceutical compositions including these tannate salts. These single dosage forms may included suspensions and tablets." (page 4, lines 12-18)

The disclosure of the preparation of a single dosage form does not sufficiently support Applicant's new claim to a plurality of dosage forms because this new limitation represents a broadening of the subject matter disclosed in the specification and claims as originally filed that does not have adequate written support. Additionally, it is noted that the very term "plurality of dosage forms" encompasses an embodiment wherein each of the active pharmaceutical ingredients is actually present in

a different dosage formulation, i.e., pyrilamine and phenylephrine in a suspension and dextromethorphan in a tablet. The concept of each of the active agents being present in multiple different types of dosage formulations is also not adequately supported by the sole disclosure of a "single dosage form", i.e., the same dosage form, in the specification and claims as originally filed.

Regarding Applicant's newly added limitations directed to "combinations thereof" of the agents recited in present claims 3, 5, 32, 34-37 and 39-43, the addition of the limitation "combinations thereof" presents a new concept into the claims that was not present in the specification and claims as originally filed. While each and every single agent recited in claims 3, 5, 32, 34-37 and 39-43 finds written support in the original disclosure, each is listed in the alternative and does not provide for the use of two or more of the agents in combination with one another. In other words, the original disclosure fails to support the concept of various "combinations" of the agents recited in the claims. This concept represents a broadening of the subject matter disclosed in the specification and claims as originally filed.

Regarding Applicant's newly added limitation directed to "at least one tablet excipient" (claim 31), Applicant teaches the process of preparing the granulation at page 13 and states, "In this embodiment, in general, the present invention features mixing of a dispersing agent, a diluent and tannic acid, as dry powders, to generate a first powder mixture. An aqueous solution of salts of the active pharmaceutical ingredients (API), phenylephrine, pyrilamine, and dextromethorphan may be sprayed on or added slowly to the dispersing agent/tannic acid mixture to generate the tannate salt. The presence of the dispersing agent prevents the clumping and aggregation of the tannate salts formed and promotes uniformity in the first powder mixture. The tannate salt of the API obtained from the above conversion process, may then be mixed with dry binding/matrix forming agents, and may be wet granulated by spraying a solution of a binder." (page 13, lines 12-22) However, the disclosure of "dry binding/matrix forming agents" at line 21 of page 13 does not provide adequate written support to broaden the claim(s) to now read upon the use of at least one of any type of tablet excipient. Applicant's disclosure of,

specifically, dry binding/matrix forming agents is of a much narrow scope than any tablet excipient known in the art. Accordingly, the concept of the use of at least of one any type of tablet excipient represents a broadening of the subject matter originally disclosed that does not have adequate written basis in the specification and claims.

Lastly, regarding Applicant's newly added limitation directed to the homogeneous suspension, granulation or composition of the active pharmaceutical ingredients (claims 1, 31 and 53), it is noted that the term homogeneous is not explicitly stated in the specification or claims as originally filed. While it is recognized that adequate written description of a newly added limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for a newly added claim limitation must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention. Applicant has once again failed to point the Examiner to those portion(s) of the specification that provide adequate written description for the concept of a homogeneous suspension, granulation or composition as now claimed in present independent claims 1, 31 and 53. Relevant disclosure was noted, however, at page 4, lines 6-10, which states, "Therefore, it would be desirable if pharmaceutical compositions containing pyrilamine, phenylephrine, and dextromethorphan tannates could be prepared with reduced variability in active drug content and increased certainty that the active pharmaceutical ingredients are delivered within a therapeutic range."

However, the disclosure of a "reduced variability" is not synonymous with now claiming homogeneity of the suspension, granulation or composition. Applicant's attention is directed to Merriam Webster Online, which defines "homogeneous" as "of the same or a similar kind or nature; of uniform structure or composition throughout" and "variable" as "able or apt to vary; subject to variation or changes" (Merriam Webster Online, 2006). It is clear from the plain meaning of the words

"homogeneous" and "variable" that the "reduced variability" that Applicant has disclosed in the specification is a term much broader in scope than the term "homogeneous" as now claimed.

Reduced variability of the active drug content is indicative of embodiments of the claimed composition wherein there is less variation or difference between the active drug content of one dosage form and another dosage form. However, homogeneous is indicative of complete or substantial uniformity among all dosage forms and, therefore, does not allow for much, if any, degree of variation. In other words, the newly added limitation to a homogeneous suspension, granulation or composition represents a narrowing of the subject matter originally disclosed in the specification and claims that is not adequately supported by the disclosure.

It is additionally noted that the disclosure found at page 4, lines 6-10, does not directly refer back to Applicant's claimed inventive composition, but rather refers to a need of compositions already known in the art. In light of such, the fact that Applicant may have expressed the need or desire for a process of making compositions comprising phenylephrine, pyrilamine and dextromethorphan with reduced variability in the active drug content does not provide adequate written support to now claim that Applicant's own inventive composition has this reduced variability in active drug content, let alone homogeneity as presently claimed.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) a plurality of active ingredients (claims 1, 31 and 53), (2) plurality of dosage units (claims 1, 31 and 53), (3) combinations thereof (claims 3, 5, 32, 34-37 and 39-43), (4) at least one tablet excipient (claim 31) and (5) homogeneous suspension, granulation or composition (claims 1, 31 and 53).

Accordingly, for these reasons, claims 1-21, 31-48 and 53 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, for the reasons of record set forth at pages 5-6 of the previous Office Action dated February 15, 2006, of which said reasons are herein incorporated by reference.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

Applicant states that, "In view of the claims as amended, Applicants note that the first listed step in the process of claim 1 recites, 'forming a solution by dissolving the salt or free base of the active pharmaceutical ingredients in a solvent.' Thus, Applicants submit that it is clear that the salts recited in claim 3 refer to those salts used in this step of the process of forming the compositions." (see paragraph bridging pages 20-21 of Applicant's remarks)

While the amendment to claim 1 has been carefully considered, it is noted that claim 3 does not explicitly refer back to the salt of said active pharmaceutical ingredient, but rather to "the active pharmaceutical ingredients", which, if interpreted in a literal manner, would actually refer back to the "active pharmaceutical ingredients" at lines 1-2 of present claim 1. In other words, the claim conceivably reads upon an embodiment wherein the composition consists essentially of the active pharmaceutical ingredients selected from the maleate, citrate, chloride, bromide, acetate and sulfate salts of phenylephrine, pyrilamine and dextromethorphan, which is clearly contradictory to the end result of the

process described in present claim 1, i.e., the formulation of a composition comprising the tannate salts of phenylephrine, pyrilamine and dextromethorphan.

Accordingly, the amendment to claim 1, while noted, does not remedy the lack of clarity in claim 3. It is suggested that Applicant may wish to amend the claims with consistent terminology to make clear those "active pharmaceutical ingredients" that are intended to be limited by present claim 3.

For these reasons, and those set forth at pages 5-6 of the previous Office Action dated February 15, 2006, rejection of claim 3 remains proper and is **maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present independent claims 1, 31 and 53 are each drawn to a composition comprising a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine, and dextromethorphan, wherein the composition is produced by the process of forming a solution by dissolving the salt or free base of said active pharmaceutical ingredients in a solvent, forming a dispersion by mixing a dispersing agent and tannic acid in a solvent and combining the solution and the dispersion to form tannate salts of the active pharmaceutical ingredients and then combining the tannate salts with at least one suspending agent without isolation or purification to produce a homogeneous suspension of the pharmaceutically active tannate salts.

In particular, Applicant's newly added limitation directed to "a plurality of active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine and dextromethorphan" does not clearly

delineate whether the "plurality" of active ingredients is limited to phenylephrine, pyrilamine and dextromethorphan only or whether the "plurality" of active ingredients is actually inclusive of the phenylephrine, pyrilamine and dextromethorphan components in addition to other active pharmaceutical ingredients that are not specified in the claim. In other words, Applicant has failed to specifically define what, if any, other active pharmaceutical ingredients are actually encompassed by the term "plurality" and how one of ordinary skill in the art would readily identify those active pharmaceutical ingredients intended to be included or excluded from the scope of the present claims.

Furthermore, Applicant's newly added limitation directed to "without isolation or purification" has been noted, but renders the claim indefinite because Applicant has failed to make clear whether the claim(s) intend that the tannate salts are not isolated or purified prior to combination with the at least one suspending agent or whether the combination of the tannate salts and the at least one suspending agent is not further isolated or purified after the step of combining the two components. In other words, Applicant has not clearly delineated on the record to which components the isolation or purification step refers.

Additionally, Applicant's newly added limitation directed to "the homogeneous suspension being in an amount including a plurality of dosage units, the homogeneous suspension being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units" is a limitation that renders the claims indefinite. For example, it is not clear what is meant by the phrase "being in an amount including a plurality of dosage units" because neither the claims nor the specification claim or disclose any method by which the skilled artisan would readily determine the amount of homogeneous suspension per dosage unit such that one would be capable of ascertaining the number of dosage units actually encompassed by the homogeneous suspension. Additionally, it is noted that the specification does not teach the formulation of a plurality of dosage units, but rather a single dosage unit (see Applicant's specification, page 4, lines 12-16), which further renders the claims

indefinite because it is unclear how a single dosage unit could be construed to possibly encompass a plurality of dosage units.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21, 31-48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordiziel (U.S. Patent No. 6,287,597; 2001) in view of Venkataraman (U.S. Patent No. 6,509,492; 2003) and Chopdekar et al. (U.S. Patent No. 5,599,846; 1997).

Gordiziel teaches a composition of pyrilamine tannate and phenylephrine tannate and a variety of additional components selected from benzoic acid, coloring, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methylparaben, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol, wherein the composition is prepared via the conventional isopropanol route and

wherein the composition is prepared in various dosage forms including tablets or suspensions, wherein every 5 ml (one teaspoon) of suspension contains 25-35 mg of pyrilamine tannate and 3-8 mg of phenylephrine tannate (column 2, lines 51-64 and Examples 1-2). Gordiziel further teaches that the antihistamines in the form of their tannate salts can be prepared using the water route as an alternative to the conventional isopropanol route (column 1, line 60-column 2, line 6).

Venkataraman teaches compositions comprising combinations of two or more therapeutic agents (col.10, lines 4-5), preferably compositions comprising tannate salts of a combination of an antihistamine, a decongestant and an antitussive (col.10, lines 4-13, particularly line 7-8), preferably wherein the composition is in the form of a suspension (col.2, lines 3-10 and col.19, lines 35-41), and wherein the antihistamine may be pyrilamine tannate (see Table 1 at col.6), the decongestant may be phenylephrine tannate (see Table 1 at col.7) and the cough suppressant/antitussive may be dextromethorphan tannate (see Table 1 at col.7). Venkataraman further teaches that the tannate compositions may be produced in very pure form via the methods described in Chopdekar et al. (U.S. Patent Nos. 5,599,846 and 5,663,415; col.6, lines 39-47).

Chopdekar et al. teaches the preparation of antihistamine tannates, i.e., phenylephrine tannate, by a synthetic route comprising contacting phenylephrine free base with tannic acid in the presence of water to precipitate the free base, recovering the precipitate, washing the precipitate with cold water and then air drying the precipitate at ambient temperatures (col.2, lines 42-53). Chopdekar et al. teaches that the yield via the disclosed synthetic route is at least about 95% compared with 70% via the conventional isopropanol route (col.3, lines 26-30) and that the purity of the tannate produced by the disclosed synthetic route is at least 99% with less than 1% water by weight of the composition (col.2, lines 24-33), compared with 85-90% purity via the conventional isopropanol route, where the balance is composed of decomposition products and isopropanol (col.2, lines 34-41).

One of ordinary skill in the art would have found it *prima facie* obvious to combine the

disclosures of Gordiziel and Venkataraman to compose a pharmaceutical composition of phenylephrine tannate, pyrilamine tannate and dextromethorphan tannate because Venkataraman teaches the preferable combination of an antihistamine, decongestant and antitussive (i.e., dextromethorphan tannate, see Table 1 at col.7) as an efficacious and comprehensive approach to treating viral infection or symptoms, cold symptoms, allergic rhinitis, runny nose, cough, post-nasal drip, rhinorrhea and sinusitis (Venkataraman, col.8, lines 5-27). The skilled artisan would have been motivated to do so in order to provide a single composition with broader therapeutic effects and an enhanced benefit to the patient. Additionally, both the compositions of Gordiziel and those of Venkataraman are each known for the same therapeutic purpose (i.e., treating the common cold, allergic rhinitis, sinusitis, etc.) and, therefore, the combination of the composition of Gordiziel with that of Venkataraman would have naturally commended itself, and have been *prima facie* obvious, to the skilled artisan. Motivation to administer two compositions flows logically from the fact that each was known to be administered for the same therapeutic endpoint and it is generally obvious to use in combination two or more agents that have previously been used separately for the same purpose. Please see *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069.

Additionally, it is noted that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the process of Chopdekar et al. for formulation of the tannate salts of phenylephrine, pyrilamine and dextromethorphan rather than the conventional isopropanol route because the process of Chopdekar et al. is capable of producing (a) a much higher yield of tannate(s) and (b) a much higher level of purity of those tannate(s), as compared with the synthetic isopropanol route. Such a person would have been motivated to do so because the enhanced yield and purity would have allowed for greater uniformity in the pharmaceutical composition and would also have enhanced the therapeutic effect of the composition while minimizing exposure to degradation products and organic solvents, which may hinder the therapeutic activity of the composition.

Though the process of Chopdekar et al. is not necessarily the same as that presently recited in the claims in the order or step by which the process proceeds, the invention as claimed is the composition of phenylephrine tannate, pyrilamine tannate and dextromethorphan tannate, regardless of how Applicant has claimed the composition is produced. Process limitations only become patentable distinctions if they confer upon the product a physical or structural property that is not found in the composition of the prior art.

In the present case, Applicant asserts that the claimed process confers a property to the composition (i.e., enhanced uniformity in the amounts of active ingredients in the claimed composition) that distinguishes the composition from the prior art. However, this property of "homogeneity" in the composition is already present in the composition of the prior art as taught by the combination of references. The synthetic process disclosed by Chopdekar et al. produces phenylephrine tannate (and can also be used for the production of pyrilamine tannate and dextromethorphan tannate according to Venkataraman, see *supra*) with at least 99% purity. This clearly meets the limitation of homogeneity of the composition since the combination and mixing of three essentially pure compounds (i.e., phenylephrine, pyrilamine and dextromethorphan, each of at least 99% purity) would necessarily produce a single composition with an exceptional level of purity (i.e., substantially free from degradation products and organic solvents) and a consistent level (i.e., uniformity) of total active pharmaceutical content in the final product.

As stated in the MPEP at §2113, "Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, *the burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.*" (emphasis added)

It has long been held that once a product has been fully disclosed in the prior art, future claims to that same product are precluded, even if that product is claimed as made by a new process. The presence

of a process limitation in the product claim, where the product does not patentably distinguish over the prior art, cannot impart patentability to that same product. It is the product itself that must be patentably distinct from the product already known in the prior art. Though a product may be claimed in terms of the process of making it, the product must still be new in structural terms in order to meet the requirement for novelty. Applicant is directed to, for example, *Gen. Elec. Co. v. Wabash Applicant Corp.*, 304 U.S. 364, 373 (1938) ("Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced").

Absent any evidence on the record demonstrating a physical or structural comparison and difference between the claimed product and that of the prior art, the combination of cited references clearly indicates that the prior art composition is the same, or substantially the same, in the uniformity of the amount(s) of active ingredients such that this new process that Applicant now claims distinguishes the claimed product from that of the prior art does not, in fact, amount to a patentable distinct difference in the physical or structural nature of the claimed composition.

Regarding the claimed wt% and dosage amounts, the determination of the optimum wt% and dosage amounts of the presently claimed active pharmaceutical ingredients that comprise the composition would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the wt% or dosage amounts that would have actually been employed would have varied widely and, in the absence of evidence to the contrary,

the currently claimed specific wt% or dosage amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentration of the active ingredients is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Furthermore, the determination of the optimum pH of the claimed liquid dosage form would also have been a matter well within the purview of the skilled artisan. Such a determination would also have been made in accordance with a variety of factors, such as modifying the pharmaceutical carriers used to formulate the dosage form to optimize palatability of the dosage form and to maximize tolerability of the composition. In addition, the skilled artisan would also have been motivated to optimize the pH of the solution in order to maintain the active pharmaceutical ingredients in their desired salt form without any degradation of the active ingredients that may occur due to a change in pH.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or

claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 31-48 and 53 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-21, 31-48 and 53 of U.S. Patent Application No. 10/047,578, for the reasons of record set forth at pages 13-16 of the previous Office Action dated February 15, 2006, of which said reasons are herein incorporated by reference.

Present claims 31-48 are properly included in the present rejection because such claims are directed also to a composition comprising active pharmaceutical ingredients consisting essentially of phenylephrine, pyrilamine and dextromethorphan.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

Applicant states that the present claims have been amended to recite that the active pharmaceutical ingredients consist essentially of phenylephrine, pyrilamine and dextromethorphan and that the inclusion of dextromethorphan in the present claims renders them non-obvious over the copending claims.

In response thereto, it is duly noted that the present claims differ from the copending claims in that the present claims are directed to a composition of phenylephrine, pyrilamine and dextromethorphan, where the copending claims are directed to a composition of phenylephrine and pyrilamine. It is clear that the present claims anticipate the copending claims because the present claims explicitly provide for a composition of phenylephrine and pyrilamine.

Regarding Applicant's disagreement with the Examiner's interpretation that the present claims allow for the inclusion of other unspecified components by reciting the term "comprising", Applicant is first reminded that the transitional phrase "comprising" is considered open language and does allow for the inclusion of additional components. However, in the present instance, the rejection is not predicated upon the interpretation that the *present* claims do not patentably exclude additional components, but

rather that the *copending* claims do not patentably exclude additional components, e.g., the dextromethorphan component. As previously stated at pages 14-15 of the previous Office Action, the transitional language "consisting essentially of" is considered open language absent a clear indication in the specification of what the basic and novel characteristics of the invention are and what components clearly alter those characteristics such that they are excluded from the scope of the claims. Absent factual evidence to the contrary, and in light of the fact that Applicant has failed to define the basic and novel characteristics of the invention, the copending claims are considered "open" to the inclusion of additional components and, therefore, do not patentably exclude the dextromethorphan component as provided for in the present claims.

For these reasons, and those previously set forth at pages 13-16 of the previous Office Action dated February 15, 2006, rejection of claims 1-21, 31-48 and 53 is proper and is **maintained**.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent No. 3,282,789, entitled "Stable Liquid Colloidal Tannate Compositions".

Rejection of claims 1-21, 31-48 and 53 is proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the

advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

October 26, 2006

Ardin H. Marschel 10/26/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER